IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	:	
MICHAEL ROREGER	:	
Serial No. 08/737,111	:	Group Art Unit 1617
Filed October 25, 1996	:	Examiner E. Webman
COLLAGEN PREPARATION FOR THE CONTROLLED RELEASE OF ACTIVE SUBSTANCES	:	

#15
Brief
2-25-99

REPLY BRIEF

Assistant Commissioner for Patents

Washington, D.C.

Sir:

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

In response to the Examiner's Answer mailed on December 23, 1998, the Appellant has the following comments.

In the Examiner's Answer, the Examiner states that the Wallace et al. reference teaches a distribution of collagen having different molecular weights. However, the Examiner has still not addressed Appellant's argument that the combination of Luck et al. with Wallace et al. fails to establish a *prima facie* case of obviousness since there is no motivation to combine these references.

There is no suggestion in the Wallace et al. reference which would suggest to one of ordinary skill in the art that the digested collagen of Wallace et al. can be used in a preparation for controlled release of an active substance. Wallace et al. is merely directed to collagen derived from either or both of two sources, bone and skin. Bone-derived collagen is prepared from demineralized bone and consists essentially of Type I collagen having the telopeptides effectively removed. This is obtained by treating demineralized bone with a non-collagenase protease, such as trypsin, which both destroys factors mediating inductive repair and removes the telopeptides. The skin-derived collagen is chiefly Type I collagen which includes a small amount of Type III and is typically obtained from calf skin. There is no disclosure or suggestion found within the Wallace et al. reference which suggests that the collagen prepared by this reference can be used in a preparation for the controlled release of an active substance.

The Appellant's claims are directed to a mixture of acid insoluble collagens or collagen fractions which have different molecular weight distribution and are obtained by an alkaline decomposition. The only teaching within the Luck et al. and Wallace et al. references of using a mixture of collagens is found in column 12, lines 26 - 30 where two collagen bone powders are mixed. However, there is no teaching or suggestion why one skilled in the art would use a mixture of the collagens. Therefore, the Wallace et al. reference does not provide any motivation to one skilled in the art to use a mixture of digested collagens in place of the collagens of the Luck et al. patent. In the absence of such motivation, the combination of Wallace et al. with Luck et al. cannot establish a *prima facie* case of obviousness.

It is noted, however, that in the statement of rejection, the Examiner states that one would select the collagens of Wallace et al. since they are purified. However, there is no motivation found in the Wallace et al. reference to use a combination of purified collagens in order to prepare a preparation for the controlled release of an active substance. Therefore, the motivation provided by the Examiner does not address all the claim limitations but merely addresses why one skilled in the art would use a collagen of Wallace et al. over the collagen of Luck et al.. Again, there is no indication that the collagen of Wallace et al. can or would be effective in a collagen preparation for the controlled release of an active substance. The combination of Luck et al. with Wallace et al. therefore fails to address how all of the Appellant's claim limitations are obvious based on the combination of references. Therefore, in the absence of some suggestion found in the prior art directing one skilled in the art towards the use of a mixture of acid insoluble collagens or collagen fractions which have different molecular weights, the combination of Luck et al. with Wallace et al. cannot establish a *prima facie* case of obviousness.

For the above reasons and the reasons stated in the Appellant's Brief filed on October 7, 1998, the presently claimed invention is patentable over the references relied upon by the Examiner.

Respectfully submitted,

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